REMARKS

The Office is respectfully requested to reexamine and allow claims 1-64 in the present merged reissue application and reexamination proceeding. The patent owner respectfully traverses the rejections of record under 35 U.S.C. Section 103 and requests that they be withdrawn, in view of this response.

All Pending Claims (35 USC 103)

All the pending claims should be allowed over the prior art of record because none of the prior art, individually or combined, takes into account the relation of the shaft dimensions and function of the catheter to the needed mechanical properties of the shaft. The Beisel reference indicates that its epidural catheters should be about 91.4 cm or 36 inches long. See page 5, lines 29-30. The mechanical properties it mentions are for a catheter of that length adapted for epidural insertion, which does not appear to involve threading the catheter through tortuous anatomy. Once the catheter enters the epidural space, the catheter is simply inserted into and through that space. Beisel, page 1, lines 21-23.

The specification of the Ainsworth '121 patent under reexamination/reissue indicates that the present angioplasty catheters (see Col. 1, lines 6-8) are much longer – about 120 to 150 cm in length (Col. 3, lines 14-16). Catheters according to the present invention serve a different purpose than epidural catheters. In particular, an angioplasty catheter 10 illustrated in the Figures of the present patent must be able to flex sufficiently to follow a tortuous path dictated by a guidewire 18 guiding the catheter through tortuous vascular passages (Col. 1, lines 45-46). The substantial length of these passages dictates a longer catheter, and increases the need for stiffness in the proximal shaft so the longer catheter will not buckle when pushed from the proximal end through tortuous anatomy encountered at its distal end.

Because the catheters of Beisel and the present patented invention are very different, it would not be obvious to provide material having the properties recited in the Beisel reference for use in the angioplasty catheters of the present invention. Given that the properties of PEEK and other engineering thermoplastics can be deliberately

modified by processing, one skilled in the art cannot merely select a material to use, but must select the properties needed of the extruded material and be aware that one can process that material as needed to get the properties required for the end use.

Additional Comments Regarding
Claims 4, 15, 36, 41-42, and 57-64 (35 USC 103)

The present rejections of at least claims 4, 15, 36, 41-42, and 57-64 should also be withdrawn for the following reasons.

First, the Examiner correctly points out that the Muni and Beisel references fail to disclose the elongation at break of the materials employed in those references. Similarly, the Cornelius reference fails to disclose any of the claimed properties. The only applied reference that mentions elongation at break is the Bennett reference. Thus, only the Bennett reference contains tensile, modulus, and elongation information for the same material samples. These properties should be considered together, as they are interrelated and vary with material processing conditions. As the Reexamination Requester asserted, on page 5 of the Request for Reexamination filed March 23, 1998 (with the underline added here):

> It is axiomatic that the tensile strength, tensile modulus and elongation properties, as recited in the claims of Ainsworth '121, are all dependent on the crystallinity of the extruded material. Ainsworth et al. admit in their response during [the prior Ainsworth '121] Reexam that it is the crystallinity that they alter during extrusion. Crystallinity stiffens the material, and a stiffer material provides a higher tensile strength, a higher tensile modulus, and a <u>lower</u> elongation."

In other words, increasing crystallinity has both good and bad effects, in terms of the present invention – it provides a high tensile strength and modulus, which are desirable here within certain ranges, but it provides a lower elongation, which is undesirable here.

Present claims 4, 15, 41-42, and 59-64 require an elongation greater than about 60%, as well as a tensile modulus greater than about 400,000 psi, which is 2.76 GPa, using the conversion factor (145,000 psi = 1 GPa) provided by the Requester of the

present reexamination. Present claims 57 and 58 similarly require an elongation greater than 50%, as well as a tensile modulus greater than about 400,000 psi.

Bennett does not disclose any materials having a tensile modulus as high as 400,000 psi. Therefore, none of the materials tested in Bennett satisfies the tensile modulus limitation of claims 4, 15, 41-42, and 57-64. The question becomes whether it would be obvious to modify the processing of the Bennett materials to achieve all the properties required by the present claims 4, 15, 41-42, and 57-64.

But if one increases crystallinity, to increase the tensile modulus above 400,000, damage is done to the elongation of the more-crystalline material. In already-stiff materials, in an application where flexibility remains essential (e.g. the vascular catheters of the present invention), it would not be obvious to increase the modulus at the expense of elongation. See the present (Ainsworth '121) patent, col. 2, lines 26-32, which indicates the importance of high elongation properties to prevent kinking. No reason is shown why a person of merely ordinary skill in the art would expect to raise the crystallinity high enough to increase the tensile modulus above 400,000, without degrading the elongation properties undesirably.

Second, claims 15, 36, and 41-42 are limited to a PEEK catheter shaft having a tensile strength of at least 14,000 psi, which is 97 MPa, using the conversion factor (145 psi = 1 MPa) provided on page 15 of the Reexamination Request. The Bennett and Beisel references – the only ones disclosing the tensile strength of PEEK – do not disclose any PEEK test materials that have a tensile strength this high.

Example 2 of Bennett, for example, shows a PEEK material having a tensile strength at break of 88 MPa, or 12,600 psi. Examples 1, 3-4, 6, 8, 10-15, and 17-22 of Bennett relate only to PEEKK, which is a different material. See Bennett, col. 1, lines 29-36 and col. 2, lines 10-15. No reason is disclosed in this reference for assuming that the tensile strength of PEEK can be increased over 14,000 psi, absent any disclosure of that tensile strength in the cited prior art.

Table I on page 7 of Beisel discloses a tensile strength for PEEK of just 93.8 MPa (13,600 psi), which also is less than 14,000. No reason is disclosed in this

reference for assuming that the tensile strength of PEEK can be increased over 14,000 psi, absent any disclosure of that tensile strength in the cited prior art.

Claims 4, 15, 36, 41-42, and 57-64, therefore, should be patented because they are not disclosed or obvious in view of the prior art, including the Beisel and/or Bennett references.

Support for New Claims 57-64

The original patent supports the limitations of added claims 57-64 at least as follows, so the present amendment does not introduce any new matter.

Claim Language	**Support in US Patent 5,554,121**
Claim 57. An intraluminal catheter	Col. 1, line 58: "This invention is directed to an intraluminal catheter"
Claim 57. for percutaneous insertion and transluminal advancement into a patient's vasculature,	Col. 1, lines 6-8: "This invention relates to the field of intravascular catheters, and more particularly to a dilatation catheter for percutaneous transluminal coronary angioplasty (PTCA)."
Claim 57 cont'd. the catheter having a shaft	Col. 2, lines 51-52: "As shown in FIG. 1 the dilatation catheter 10 of the invention generally includes an elongated catheter shaft 11"

Claim Language	Support in US Patent 5,554,121
Claim 57 cont'd. [the shaft] comprising: a) a proximal shaft portion formed at least in part of an extruded thermoplastic polymeric material	Col. 3, lines 3-4: "The outer tubular member 16 has a relatively stiff proximal portion 20 formed of a requisite linear aromatic polymer" Col. 2, lines 59-62: "... at least part of the shaft thereof formed of a melt processable engineering thermoplastic polymer material and preferably an aromatic polymer. The melt processed, e.g. extruded, thermoplastic polymer...."
Claim 57 cont'd. [the extruded thermoplastic polymeric material] with an elongation greater than 50% and	Col. 1, lines 61-64: "The melt processed, e.g. extruded, thermoplastic polymer has ... an elongation at break greater than 50%...."
Claim 57 cont'd. [the extruded thermoplastic polymeric material having] a tensile modulus greater than 400,000 psi;	Col. 1, lines 61-66: "The melt processed, e.g. extruded, thermoplastic polymer has ... a tensile modulus greater than 300,000 psi, preferably greater than 400,000 psi."

Claim Language	**Support in US Patent 5,554,121**
Claim 57 cont'd. and [the shaft comprising] b) a distal shaft portion that is more flexible than the proximal shaft portion.	Col. 3, lines 8-10: "The distal portion 21 of the outer tubular member 14 is formed of a melt processable more flexible polymer material such as polyethylene or Hytrel®."
Claim 58. The catheter of claim 57, wherein said extruded thermoplastic polymeric material comprises a polyetheretherketone.	Col. 3, lines 37-43: "In a presently preferred embodiment the proximal portion 20 of the outer tubular member 16 is formed of PEEK (Grade 381 G) from Victrex USA. The resin is readily extruded at a temperature of about 750° to about 800°F. at a pressure of about 2800 psi into thin walled tubing suitable for the outer tubular member forming the proximal portion of the catheter shaft."
Claim 59. The catheter of claim 57, wherein said extruded thermoplastic polymeric material has an elongation greater than about 60%.	Col. 1, lines 61-65: "The melt processed, e.g. extruded, thermoplastic polymer has ... an elongation at break ... preferably greater than 60%...."

Claim Language	**Support in US Patent 5,554,121**
Claim 60. The catheter of claim 59, wherein said extruded thermoplastic polymeric material comprises a polyetheretherketone.	Col. 3, lines 37-43: "In a presently preferred embodiment the proximal portion 20 of the outer tubular member 16 is formed of PEEK (Grade 381 G) from Victrex USA. The resin is readily extruded at a temperature of about 750° to about 800°F. at a pressure of about 2800 psi into thin walled tubing suitable for the outer tubular member forming the proximal portion of the catheter shaft."
Claim 61. The catheter of claim 59, wherein said extruded thermoplastic polymeric material has a tensile strength greater than 10,000 psi.	Col. 1, lines 61-63: "The melt processed, e.g. extruded, thermoplastic polymer has a tensile strength greater than 10,000 psi...."

Claim Language	**Support in US Patent 5,554,121**
Claim 62. The catheter of claim 61, wherein said extruded thermoplastic polymeric material comprises a polyetheretherketone.	Col. 3, lines 37-43: "In a presently preferred embodiment the proximal portion 20 of the outer tubular member 16 is formed of PEEK (Grade 381 G) from Victrex USA. The resin is readily extruded at a temperature of about 750° to about 800°F. at a pressure of about 2800 psi into thin walled tubing suitable for the outer tubular member forming the proximal portion of the catheter shaft."
Claim 63. 63. (Pending) The catheter of claim 59, wherein said extruded thermoplastic polymeric material has a tensile strength greater than 14,000 psi.	Col. 1, lines 61-63: "The melt processed, e.g. extruded, thermoplastic polymer has a tensile strength ... preferably greater than 14,000 psi...."

Claim Language	Support in US Patent 5,554,121
Claim 64. The catheter of claim 63, wherein said extruded thermoplastic polymeric material comprises a polyetheretherketone.	Col. 3, lines 37-43: "In a presently preferred embodiment the proximal portion 20 of the outer tubular member 16 is formed of PEEK (Grade 381 G) from Victrex USA. The resin is readily extruded at a temperature of about 750° to about 800°F. at a pressure of about 2800 psi into thin walled tubing suitable for the outer tubular member forming the proximal portion of the catheter shaft."

Claim Interpretation

The patent owner agrees with the Examiner that the phrase "proximal shaft portion formed at least in part of [defined extruded material having defined properties]" is definite, contrary to the assertion by the reexamination requester on page 4 of the present reexamination request that it is not definite as construed by the patent owner to address the physical properties of the material after extrusion into a catheter component.

The requester complains, without any supporting evidence, "It would be very difficult or impossible to test the tensile strength, tensile modulus, and elongation of a particular thermoplastic material after extrusion using one of these composite catheter tubing samples [i.e. 'coextruded material layers' or 'a braid']." The Patent Owner disagrees, to the extent this objection is even understood, since the requester did not explain what specific structure it has in mind that would be difficult to test for material properties. The Patent owner suggests the following ways to evaluate the mechanical

properties of a coextruded material or a braid including a material as defined in the claim and another layer.

Starting with a braid, which is understood to refer to several strands of one or more materials braided together to define a shaft portion, no reason is evident why a PEEK strand extruded by an accused infringer or other supplier under the same conditions used to make the PEEK strand(s) of a commercial catheter could not be tested for mechanical properties, without actually incorporating it in a catheter first.

Similarly, for a coextruded shaft formed of coaxial layers of PEEK and some other material expressed from different extrusion dies and joined together, the material properties of the coextruded PEEK portion might be evaluated by running the extruder while feeding the PEEK but without feeding the other material, under the same processing conditions, so the PEEK portion alone was extruded. Or the PEEK material might be run, at the same conditions, though both dies for the purpose of the experiment, providing a uniform material.

This explanation is not meant to provide all ways, or even the best or most appropriate way, of determining whether a catheter is within the claimed invention, but illustrates that the required measurement is not necessarily "difficult" or "impossible" for a braided or coextruded construction.

Moreover, the recitation of a "proximal shaft portion formed at least in part of [defined extruded material having defined properties]" is broad enough to cover co-extruded, braided, or other constructions formed in part of the defined material and in part of another material.

The specification illustrates an embodiment in which the cross-section of the proximal shaft portion is made of PEEK, the cross-section of the distal shaft portion is made of another material, and both materials overlap to define a transition (shown at section lines 3—3 of Fig. 2, as called out in Fig. 3). But nowhere does the specification of the original patent limit the invention to this embodiment.

In addition, "formed at least in part of," in claim 1, can also be interpreted as meaning that, in a coaxial catheter with inner and outer tubular members, the "shaft portion" is a proximal part of the entire catheter, including both inner and outer tubes,

and "formed in part of" means that the inner tube can be the material defined in claim 1 and the outer tube can be made of other material, or vice versa. Certainly, an outer tube formed of PEEK, assembled with an inner tube of another material, does not avoid the claims, as this embodiment is expressly contemplated. See Col. 2, lines16-20.

Moreover, a comparison of original claims 1 and 5 shows that claim 1 recites a shaft portion "formed at least in part of an extruded engineering thermoplastic polymeric material," while claim 5 depending from claim 1 describes a shaft portion "formed of the extruded engineering thermoplastic polymeric material." "Formed of" is a narrower version of "formed at least in part of," indicating that claim 1 is not limited to mean "formed entirely of."

It would not be reasonable to adopt the requester's proposed artificially narrow construction of original claim 1, allowing the requester or other competitors the option to avoid the patent simply by coextruding a thin outer coating of any other material on a shaft portion made of extruded engineering thermoplastic material as defined in the present claims. The patent owner does not agree with the claim construction proposed in the Office action, but it is not necessary now to establish exactly what the claims may be found to mean in court. It is enough to show the error of the requester's assertion that it would be "difficult or impossible" to measure the properties of the extruded polymer, according to artificial examples proposed by a competitor to limit the legitimate reach of the present patent.

Finally, the fact that this claim is being examined by a mechanical engineering group does not change its meaning. It means what a person skilled in this art would understand it to mean. The Examiner should give the claim its broadest reasonable construction during prosecution.

Conclusion

For the reasons stated above, claims 1-64 should be allowed.

Respectfully submitted,

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George Wheeler
Reg. No. 28,766

Attorney for applicant(s)

McAndrews, Held & Malloy, Ltd.
34th Floor
500 West Madison Street
Chicago, IL 60661
312/775-8000